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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,817	01/23/2002	Rudolph E. Tanzi	0609.4460005	4182

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,817

Applicant(s)

TANZI ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 and 65-76 is/are pending in the application.
- 4a) Of the above claim(s) 11, 14-26, 30-50 and 65-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 13 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a divisional of US Application 09/241,606, filed February 2, 1999, now US Patent 6,472,140, which is a continuation in part of Application 09/148,503, filed September 4, 1998, now US Patent 6,342,350, which claims priority to US provisional applications 60/057,655, filed on September 5, 1997 and 60/093,297, filed on July 17, 1998.

Claims 1-50, 65-76 are pending and currently under examination.

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on June 16, 2004 is acknowledged. The traversal is on the ground(s) that individual claims are in multiple groups and that Applicants can not recover their entire scope as presently restricted (page 1-3). Further, it is argued that replacement of function would also be considered a form of supplementing and would not be considered a serious burden. This is not found persuasive because as set forth in the restriction requirement the office has set-up the relationship of groups I-III as linking claims where claim 1 link(s) inventions I- III. It was stated that the restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims

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of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. Therefore, Applicants' arguments that the full scope of the invention can not be recovered is not persuasive because upon the allowability of claim 1, the full scope of the claimed invention, will have been reviewed and considered.

With respect to arguments that groups I and II are related in that replacing would sometimes also supplement function for example when one would administer anti-LRPA β to a patient completely lacking α_2 M (Applicants' amendment, page 3). Examiner acknowledges this particular example, however as indicated in the restriction requirement the search and consideration of each of these are not coextensive because they are unrelated. As stated in the restriction requirement, inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to agents with materially different functions with no indication that a single agent will perform all functions. While Applicants' specific example of anti-LRPA β is true, this analogy does not extend to all other potential molecules and all other circumstances because of the difference required in 'replacing' and 'supplementing' function are considered to be different and not co-extensive. The supplement of function would not necessarily replace function. However, since dependent claims are drawn to specific anti-LRPA β molecules, and because no other function is set forth in the dependent claims, and the broadest claim 1 recites only an affect

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on α_2 M function the issues regarding the claimed invention should be the same. Therefore, the restriction requirement between Groups I and II is withdrawn

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-50, 65-76 are pending. Claims 11, 14-26, 30-50, 65-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 16, 2004. Claims 2-10, 12, 13, 27-29, drawn to a therapeutic agent for combating Alzheimer's disease wherein the agent can replace and/or supplement α_2 M function is currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) **in the first sentence** of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior

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nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. The present specification makes the priority claim starting at line 10, after a description of the invention.

Specification

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. Applicant's attention is directed to the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

37 CFR 1.821(d) states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims, even if the sequence is also embedded in the text or the description or claims of the patent application. Specifically, neither figure 6 nor the short description of the figure contains a sequence identifier for the sequence displayed in the drawing.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12, 13, 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by NCBI entry CAA 01532 (August 22 1994).

Upon review of the specification the specific sequences set forth and claimed are of alpha 2-macroglobulin (for example page 25, starting on line 25). NCBI entry CAA 01532 is the sequence of human alpha 2-macroglobulin. In view of the open language of the instant claims for comprising, the instant claims read on alpha 2-macroglobulin previously disclosed in the art.

Conclusion

No claim is allowed.

The art teaches that alpha-2 macroglobulin is associated with Alzheimer disease, however there is no teaching in the art that alteration of the ratio of A2M-1 mRNA to A2M-2 mRNA, or decreasing the amount of A2M-2 mRNA would reduce the production of and altered alpha 2 macroglobulin protein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach

Joe Voitach
AU 1632